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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,464	02/07/2002	Gregory R. Collins	1508/1124US1	1828

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EXAMINER

KIM, SUN U

ART UNIT	PAPER NUMBER
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1723

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,464

Applicant(s)

COLLINS ET AL.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-36 and 38-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38-46 is/are allowed.
- 6) ☒ Claim(s) 2-6, 18, 47 and 48 is/are rejected.
- 7) ☒ Claim(s) 7-17 and 19-36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

1. Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Recitation of "the control module" in claims 2-3 lacks a positive antecedent basis.
2. Claims 2, 4-5, 18 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over European Patent Application No. 0526152 A1 (hereinafter referred to as EP '152). EP '152 teaches a hemodiafiltration system comprising a first conduit (6) having a first end and an opposing second end, the first end receiving first fluid or dialysate fluid from dialysis machine and the second end for discharging dialysate fluid to a dialyzer (2) and a second conduit (8) in selective communication with the first conduit (6) to divert amount of first fluid from the first conduit (6) through at least one sterilizing filter (27) via a substitution fluid pump (14) to produce a substitution fluid and a central control unit (21) responsive to flow rate of first fluid in the first conduit (6) and a returning fluid in duct (7) detected by a flow meter (16) (see figure 1; col. 2, line 56 – col. 4, line 46) wherein the central control unit (21) controls dialysate pump (12) and substitution pump (14) in such a way that the sum of these quantities flows in the first tube of the flow meter (16) (see col. 4, lines 21-28) (claims 2, 5, 18). Regarding claim 4, EP '152 inherently teaches a flow meter in an extracorporeal circuit (4, 5) because EP '152 teaches that data relating to the quantity of blood put into circulation by the pump (11) is also set into the central control unit (21). Claims 2, 4-5, 18 and 47-48 essentially differ from apparatus and method of EP '152 in reciting an independent standalone detachable diafiltration module. EP '152 suggests from the figure 1 that tubes, pumps, filters and control unit are separate from extracorporeal circuit and dialysis machine supplying dialysate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an independent

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standalone detachable diafiltration module containing tubes, pumps, filters and control unit from extracorporeal circuit and dialysis machine, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

3. Claims 2-6, 18 and 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/06292 in view of U.S. Patent No. 6,284,141 (hereinafter referred to as Shaldon et al). WO 00/06292 teaches a hemodiafiltration method and system comprising a first conduit (41) having a first end and an opposing second end, the first end receiving first fluid from dialysis machine (43) and the second end for discharging dialysate fluid to a dialyzer (22) and second conduit (2) in selective communication with the first conduit (41) to divert amount of first fluid from the first conduit (41) through at least one sterilizing filter (11, 13) via a substitution fluid pump (8) to produce a substitution fluid and control unit (40) responsive to flow rate of diverted first fluid via a flow meter (10) and a flow rate of blood via a flow meter (26) to control a substitution fluid pump (8) wherein the control unit (40) also receives signals from pressure sensors (9, 132) which are located upstream and downstream of substitution fluid pump (8) in the second conduit (2) (see figure 1; page 3, lines 19-21; page 7, line 7 – page 12, line 25). WO 00/06292 further teaches that the pressure en route to dialysate pump (153) in the first conduit (41) may be monitored by a pressure transducer (152) upstream of pump (153) (see page 9, lines 20-25). Pressure and flow rate in a conduit are well-known related quantities in the art of measurement. Claims 2-6, 18 and 47-48 essentially differ from the apparatus of WO 00/06292 in reciting a first flow meter disposed within the first conduit for detecting a flow rate of one of the first fluid and the dialysate fluid and in communication with the control unit in an

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independent standalone detachable diafiltration module. WO 00/06292 suggests from the figure 1 that tubes, pumps, filters and control unit are separate from extracorporeal circuit and dialysis machine supplying dialysate. Shaldon et al teach a hemodiafiltration apparatus comprising a first flow meter (10) disposed within the first conduit for detecting a flow rate of one of the first fluid and the dialysate fluid and in communication with the control unit (14) and a second conduit (16) in selective communication with the first conduit and having a pump (17) for providing a substitution fluid to an extracorporeal circuit (see figure 5; col. 7, line 18 – col. 8, line 35).

Shaldon et al teach that signal from the flow meter (10) and other inputs are fed to a control unit (14) for determining efficiency (see col. 7, lines 18-57). It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute a first flow meter for a pressure transducer within the first conduit of WO 00/06292 for detecting a flow rate of dialysate fluid and determining efficiency as suggested by Shaldon et al and provide an independent standalone detachable diafiltration module containing tubes, pumps, filters and control unit from extracorporeal circuit and dialysis machine, since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

4. Claims 7-17 and 19-36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Claims 38-46 are allowed.

6. Applicant's arguments with respect to claims 2-36 and 38-48 have been considered but are moot in view of the new ground(s) of rejection.

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7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-1142. The examiner can normally be reached on weekdays from 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (571) 272-1151. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


John Kim
Primary Examiner
Art Unit 1723

J. Kim
October 14, 2004